

II. Support for the Claims

Support for the instant claims can be found throughout the specification as filed and the original claims.

In light of the present changes to the claims, it seems most logical and efficient for the pending claims to be canceled and replaced by a new series of consecutively numbered claims. Cancellation of the former claims has thus been undertaken for the convenience of the Examiner and in no way represents abandonment of the subject matter recited therein.

The new claims have been grouped together according to subject matter, as suggested in the MPEP, but have a close correlation with the claims pending prior to the present response. **Exhibit B** is provided in order to succinctly identify the support in the former claims for the new claims. The only changes within the new claim set that do not correlate exactly with the former claims are supported as follows.

In claims 110 and 113, the "contiguous sequence of at least about 16 amino acids" from the recited sequences is supported by the specification at least at page 16, lines 27-28; at page 17, lines 20-21; at page 19, lines 4-5; and at page 20, lines 1-2. The hybridization terminology formerly within claim 1 is now reserved for a separate independent claim (claim 137).

In the following claims, contiguous sequences "of at least about 18, 25, 40, 60, 70, 80, 90 or 125 amino acids" from the recited sequences are supported by the specification at least at page 16, line 27 through page 17, line 2 and at page 19, lines 9-10.

Claim 137 is supported by original claim 1 and claim 11, but now uses even more definite language of the format recently said to be allowable by the P.T.O. in another pending application (Serial No. 08/479,722).

In claims 138-143, the nucleotide sequences "of at least 21, 30, 40, 50, 60 or 72 contiguous nucleotides" present in the recited sequences are referenced in the specification at least at page 17, lines 10-11 and at page 19, lines 19-21.

Nucleic acid molecules of "up to about 10,000 or about 5,000 basepairs in length", as in claims 147 and 148, are supported by the specification at least at page 25, line 21.

Nucleic acid sequences that encode functional P-TEFb kinase subunit polypeptides that exhibit at least 90% identity (or between 91% and about 99% identity) to the recited amino acid sequences, as in claims 149-151, are defined in the specification at least at page 61, lines 17-23. The P.T.O. also recently approved this type of identity language for allowance in pending application Serial No. 08/479,722.

Claim 152 is based upon original claim 15, re-drafted in independent form.

Support for the subsequent claims exists in the earlier claims and in the sections of the specification referenced above. Applicant has made sure that the nucleic acids within the expression system claims are defined to encode a polypeptide, as suggested in a recent telephone interview.

In light of the foregoing information and **Exhibit B**, it will be understood that no new matter is included within any of the new claims.

III. Interview Summaries

After receiving the second Official Action, Applicant's representative, Shelley Fussey, telephoned Examiner Tung to discuss matters in detail. Applicant's position was that, although the second Official Action was quite lengthy, there appeared to be patentable subject matter and

that working closely with the Examiner could lead to a timely and cost-effective resolution. Applicant thanks Examiner Tung for his productive participation in the interviews.

Applicant first drafted and forwarded for the Examiner's review three independent claims to cover the patentable subject matter from different angles. After initial progress, Applicant then drafted and forwarded for review a complete set of claims that integrated various independent and dependent claims in accordance with Sample Claims A, B and C.

Sample Claims A, B and C, can be summarized as defining the P-TEFb nucleic acids according to: **(A)** nucleic acids that encode defined contiguous amino acid sequences from SEQ ID NO:4, 45, 47 or 50; **(B)** nucleic acids that encode functional polypeptides of at least 90% identity to the recited sequences; and **(C)** nucleic acids from cDNA libraries that hybridize to SEQ ID NO:3, 43 or 48 under high stringency conditions.

During a series of interviews, it was agreed that Sample Claim A, reproduced herein as claim 110, and also succinctly represented by claim 113, was allowable. It was also agreed that the dependent claims through claim 136 would be allowable, pending the Examiner's confirmation of written description support in the specification for the precise numbers recited and confirmation of clerical accuracy.

However, Examiner Tung expressed concerns regarding the clarity of the "high stringency" hybridization conditions of Sample Claim C, reproduced herein as claim 137; and with the clarity of the "90% identity" language of Sample Claim B, reproduced herein as claim 149. Applicant's representative urged that these claims should be allowable under 35 U.S.C. § 112, second paragraph for a variety of reasons, such as the frequent issuance of such language in U.S. patents and the fact that this language was recently agreed to be patentable in another application pending in Group Art Unit 1646 (Serial No. 08/479,722).

A number of separate teleconferences were then held with Examiner Tung and SPE Achutamurthy. During the interview process, Applicant identified and forwarded for review excerpts from a number of recently issued U.S. patents with "% identity" terminology similar to that at issue in the present case.

As agreement on the clarity of "high stringency" and "90% identity" could not readily be reached, on September 29, 1999 SPE Achutamurthy suggested that Applicant file a response including all contested claims, as well as those agreed to be allowable, and that the Office would carefully reconsider the clarity issues. Applicant thus proceeds as invited.

IV. Summary of Response

The language of Sample Claim A, agreed to be patentable, is reproduced herein as claims 110 and 113. Claims 110-136 are therefore believed to be in condition for allowance.

As the only remaining issues from the entire set of claims forwarded for review concern the clarity of the terms "high stringency" and "90% identity", on September 29 SPE Achutamurthy advised the Applicant to focus his response on these issues. Applicant believes that the following reasoning and evidence will overcome the clarity concerns and therefore urges that all pending claims be progressed to allowance. However, should there be any remaining concerns, Applicant encourages Examiner Tung to telephone the undersigned representative so that any such concerns can be allayed in a timely and cost-effective manner.

V. Claim Objections

The Action objected to certain former claims as being mis-numbered. Applicant apologizes for this oversight and has taken care to correctly number the present claims.

The Action also objected to the term "P-TEFb", but recent discussions suggested this term to be acceptable as used in the context of the present claims.

**VI. Rejection of Claims 1, 4, 5, 11, 15, 96, 103 and 106
Under 35 U.S.C. § 112, Second Paragraph**

The Action rejected claims 1, 4, 5, 11, 15, 96, 103 and 106 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite and for failing to particularly point out and distinctly claim the subject matter of the invention. Although Applicant respectfully traverses, the stated concerns have been addressed and agreement already reached on most issues.

In particular, the complained of terms "characterized as", "specifically", "includes", "comprised on", "comprised on two distinct vectors" and "substantially full length" have been removed from the claims (Action at paragraphs 6, 7, 8, 10, 11 and 15). The claims covering one and two subunits have been differentiated (Action at paragraph 9); the vectors have been even better defined to include a coding region and a promoter (Action at paragraph 13) and the host cells are better defined (Action at paragraph 12). The foregoing changes are clearly shown in **Exhibit B**, which correlates the new claims with former claims 1, 4, 5, 11, 15, 96, 103 and 106.

In terms of "stringent hybridization conditions", the Action first takes the position that the term stringent conditions is a "relative term" that renders the claims indefinite (Action at paragraph 14). There is no prohibition against using relative terms to define an invention. Of particular relevance to the present situation, where there are no art rejections whatsoever, it has recently been held that a "patentee has particular latitude in the use of relative terms in his claim where, as here, the prior art is remote from the claimed invention". *Hay & Forage Industries vs. New Holland North America Inc.* (D.C. Kan., No. 97-2150, 1998).

The Action next takes the position that the term stringent conditions is not "defined" by the claims. The Federal Circuit has repeatedly held that it is the role of the specification, not that of the claims, to describe the invention. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ 2d 1081, 1088 (Fed. Cir. 1986).

It is next alleged that "the specification does not provide a standard for ascertaining the requisite degree [of stringent hybridization conditions]". First, as stringent nucleic acid hybridization is a routine technical operation frequently practiced in the art, the claims need not elaborate on this issue. A patent need not teach, and preferably omits, what is well known in the art. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986). Second, the specification would indeed provide the requisite standard for stringent hybridization to one skilled in the art. "[I]f the claims, read in the light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 225 USPQ 634, 641 (Fed. Cir. 1985; emphasis added).

Importantly, the entire reasoning in the Action falls down with the statement that "various other ways of performing a hybridization under stringent conditions are possible" (Action at bottom of page 4). As those of skill in the art clearly know various ways of performing stringent hybridization, the Office has not met the burden of proof necessary to show that one of skill in the art would find the present claim language to be indefinite.

Concerning the "% identity" issue discussed during the recent teleconferences, Applicant stresses that the Office recently indicated this exact language to be allowable in an application with similar written description support to that in the present case (see application Serial

No. 08/479,722). Also, Applicant refers to **Exhibit C**, which clearly lists a number of issued U.S. patents where the "% identity" language is present in the issued claims.

Exhibit C shows that 300 U.S. patents have issued in which the broad claim includes the terms "nucleic acid, gene or DNA" and the terms "identity or identical". Although the computer program used to generate **Exhibit C** could not search the term "%" (as it is not a word), a cursory review of just a few of the 300 records reveals many issued claims that define nucleic acids simply in terms of their "% identity" without any further qualification.

The MPEP has long indicated that uniform standards of patentability must be adhered to ("the standards of patentability applied in the examination of claims must be the same throughout the office"; MPEP at page 700-8, column 1). The Federal Circuit has recently emphasized this fact, indicating that the P.T.O.'s interpretation of a claim term should not "conflict with the meaning given to identical terms in other patents". *In re Cortright*, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999). See also, *Hay & Forage Industries vs. New Holland North America Inc.*, *supra*, commenting on the support from prior art patents that use terms "similar" to those at issue.

Accordingly, as the "90% identity" language was sufficiently definite to be issued in numerous U.S. patents, this language must also be accepted as definite in the present case.

The § 112, second paragraph rejections as a whole are thus overcome and should be withdrawn.

VII. Rejection of Claims 23-26, 77-99, 101 and 109
Under 35 U.S.C. § 112, First Paragraph

The Action next rejected claims 23-26, 77-99, 101 and 109 under 35 U.S.C. § 112, first paragraph, as allegedly not being supported by an enabling specification. Although Applicant

respectfully traverses, the stated concerns were agreed to have been overcome by the draft claims forwarded for review and now reproduced herein.

Applicant has studied in detail the reasoning set forth at paragraphs 19, 20, 21 and 22 and agrees with Examiner Tung and SPE Achutamurthy that the present claims fully address the concerns earlier set forth in the first and second Official Actions. Indeed, the Second Action itself includes several indications that the specification enables the full scope of the claims sought (see, *e.g.*, Second Action at page 6, lines 2-5 and bridging pages 7 and 8).

The § 112, first paragraph rejection as a whole is therefore overcome and should be withdrawn.

VIII. Conclusion

This is a complete response to the referenced Official Action. In conclusion, Applicant submits that, in light of the foregoing remarks, the present case is in condition for allowance and such favorable action is respectfully requested. Should Examiner Tung have any questions or comments, or believe that certain amendments of the claims might serve to even further improve their clarity, a telephone call to the undersigned Applicant's representative is earnestly solicited.

Respectfully submitted,



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